REMARKS

Claims 1-28 are pending in this application. Claims 1, 4, 8, 11, 18, 22, and 25 are amended. Applicant thanks the Examiner for pointing out the allowable subject matter recited in claims 6, 13, and 27. These claims are now canceled, the subject matter incorporated in claims 1, 8, and 22, respectively. Applicant has added new claims 29-41. No new matter is presented.

Support for new claims 29-31 is found at paragraph [0087] of the specification. Support for new claim 32 is found at paragraph [0089]. Support for new claim 33 is found in original claim 1, the allowable subject matter of original claim 6 and paragraph [0089] of the specification. New claim 34 has support in paragraphs [0112] to [0114] of the specification. Claim 35 has support in paragraphs [0117], [0132], and [0133]. New claim 36 has support in paragraphs [0118] to [0120]. New claim 37 has support in paragraphs [0121], [0123] and [0130]. Support for claim 38 is found in paragraphs [0128] and [0129]. Claim 39 is supported at paragraph [0135]. Claims 40 and 41 have support in paragraphs [0137] to [0142].

A longstanding problem in the art of medical databases that correlate adverse drug effects is that it is difficult to minimize the "surrounding background 'noise' that obscures connections among data elements." (See specification, paragraph [0137].) The claimed invention resolves this problem by selecting a substance of interest, inputting data from various commonly used adverse drug effects reporting databases such as the U.S. FDA's Adverse Event Reporting System (AERS) or Medical Dictionary for Regulatory Activities (MedDRA), cleaning the data, and profiling the cleaned data. In the claimed profiler, according to one embodiment, various aspects of the target drug are compared with "concomitant drugs," a concomitant drug being a drug that may or may not be suspected of causing a bad reaction for a patient reported in one of the adverse reporting databases. (See specification, paragraph [0123].) Until applicant made the claimed invention, other attempts at removing or diminishing the "background noise" that is disclosed in applicant's specification were unsuccessful because raw data from adverse effects reporting databases included too much verbatim information. (The term verbatim means, for

example, misspellings, variations in spellings, or generic names for the same drug.) Previous attempts at removing or diminishing such verbatim information failed, the reason being that data was insufficiently "cleaned" prior to data mining efforts. Insufficient cleaning caused the raw data to produce incorrect analysis of a drug's effects. In other words, useful drug interactions were obscured. For example, the raw data cleaned by other systems was obscured or skewed so that the output data either a) failed to identify a drug that caused a bad reaction or b) incorrectly identified a drug as causing patients of a particular age or gender to have a bad reaction to the drug or combination of drugs ingested. (See specification, paragraph [0111]-[0112].) A person of ordinary skill in the art of medical databases would call these types of information "false negatives" or "false positives," respectively. Since the data input in those prior attempts was unsatisfactory, it necessarily follows that the output results did not reliably present and predict clear and useful connections between a drug and a reaction or an age and an outcome, for example.

Another problem in the art occurs specifically in relation to the pharmaceutical business. Drug companies typically conduct pre-market studies of drugs that often overlook multi-dimensional risk factors of drugs. (See specification, paragraph [0006] to [0008].) The studies may only test either men or women, or it may sample only participants of a certain age. The studies tend to be over-simplified, controlling for just one factor, such as age or gender, whereas several contributing factors (age, gender, pre-existing conditions) may cause a bad reaction to a substance that is offered for sale on the marketplace. Common problems in pre-market studies involve over-representation or under-representation of a certain group (demographic), or the study size may simply be too small to identify problems with a drug. Further exacerbating the situation with new drugs coming to market is that currently, there is rarely an after-market comparison or check of the findings of a pre-market study. Initially, drug companies will create a drug study in the pre-market environment only for men, only for women, or only for adults. Following FDA approval and release in the marketplace, doctors may eventually prescribe the

same drug to women or children, categories of patients who were not previously included, or even contemplated, in a pre-market study. The invention as claimed overcomes these limitations of the pre-market control studies that pharmaceutical companies use in the pre-market environment because the invention takes in data from both pre-market and post-market studies, cleans the data of verbatim information and compares the pre-market and post-market information concerning the drug of interest. In its various embodiments, the claimed invention is capable of manipulating data in multi-dimensional analyses.

Claims 4, 11, 18, 20, 21, and 25 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that the phrase "characteristics in drug/reaction/demographic information" is indefinite. The Examiner interprets this phrase to be "involving at least one of drug information, reaction information and demographic information." Applicant has amended the claims accordingly. Support for these amendments is found at paragraph [0029] of the specification. No new matter is presented. Therefore, the rejection should be withdrawn.

Claims 1, 4, 7-8, 11, 14-15, 18, 21-22, 25, and 28 are rejected under 35 USC 102(b) as being anticipated by Szarfman. Applicant traverses this rejection and submits that the Szarfman reference does not disclose all the elements of the claims as suggested by the Office Action, and Applicant does not acquiesce to any statements in support of the 102(b) rejection. However, Applicant has amended independent claims 1, 8, and 22 to incorporate the limitations of claims which were indicated as allowable over Szarfman. Therefore, the rejection is moot. Accordingly, claim 1 is allowable.

Since claims 1, 8, and 22 are allowable, the claims depending therefrom are allowable.

Early action soliciting allowance of claims 1-5, 7-12, 14-26, and 28-41 is requested.

In view of the above, each of the claims in this application is in condition for allowance. Accordingly, applicant solicits early action in the form of a Notice of Allowance.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. **597932000700**.

Respectfully submitted,

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